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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,432	12/06/2001	Shau-Chi Chi	39734-176754	8720

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EXAMINER	
SCHEINER, LAURIE A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,432	CHI, SHAU-CHI	
	Examiner	Art Unit	
	Laurie A. Scheiner	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8,10-14,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-8 and 10-18 are pending.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4 and 5 rejected under 35 U.S.C. 102(b) as being anticipated by Dorson et al. (Journal of Fish Diseases 1978, 1, 309-320).

Dorson et al. clearly teach an immunologically effective amount of an infectious pancreatic necrosis virus (IPNV) vaccine for immunizing trout. Dorson et al. anticipates that which is claimed since a product-by-process claim (product-by-process due to the recitation of "wherein said IPNV is produced in an immortal cell line . . .") is directed toward the product rather than the process; therefore, the product itself must satisfy novelty and unobviousness requirements. In In re Brown, 459 F.2d 531 (C.C.P.A. 1971) it was noted that "it is the

patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable." Further, where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. Applicants have provided no such evidence commensurate in scope with their claims. Please also see Ex Parte Gray, 10 U.S.P.Q.2d (BNA) 1922 (Bb. Pat. App. & Interferences 1989).

Again, Applicant fails to meet their burden of showing that the products as claimed differ from the art products, regardless of the process limitations. The products of the reference appear to be the same or obvious or analogous variants of the products broadly and non-specifically claimed by applicant because they appear to possess the same or similar functional characteristics. Since the Patent Office does not have the facilities for examining and comparing Applicant's products with the products of the prior art reference, the burden is on Applicant to show an unobvious distinction between the material structural and functional characteristics of the claimed products and the products of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (C.C.P.A. 1977).

The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change the properties of the product in an unexpected manner. See In re Thorpe, 777 F.2d 695, 227 U.S.P.Q.964 (Fed.Cir. 1985); In re Marosi, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); In re Brown, 459 F.2d 531, 173

U.S.P.Q. 685 (C.C.P.A. 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the product taught by the prior art. See In re King, 107 F.2d 618, 43 U.S.P.Q. 400 (C.C.P.A. 1939); In re Merz, 97 F.2d 599, 38 U.S.P.Q. 143 (C.C.P.A. 1938); United States v. Ciba-Geigy Corp., 508 F.Supp. 1157, 211 U.S.P.Q. 529 (D.N.J. 1979).

Claims 1, 3-5, 8 and 10-14, 17 and 18 rejected under 35 U.S.C. 102(e) as being anticipated by Vakharia et al. (US Patent 6,274,147 B1)

Vakharia et al. anticipate that which is claimed. Vakharia et al. teach both live, non-pathogenic infectious pancreatic necrosis virus (IPNV) vaccines and inactivated IPNV vaccines. Nodavirus (which comprise various NNV species) chimeric vaccines are also taught (please see claim 21). Please see Nishizawa et al. (Applied and Environmental Microbiology, April 1997, p. 1633-1636) for teaching fish nodaviruses as the causative agents of viral nervous necrosis. That is, nervous necrosis virus (NNV) as claimed is a generic class of virus that includes SJNNV, TPNNV, BFNNV and RGNNV, and is synonymous with nodavirus. Applicants are reminded that the instant claims are of the product-by process type (please see above) as well as very broadly drafted. As such, the product per se, rather than the process of making (and/or using) is anticipated by the art. Again, due to breadth of claim language, a NNV chimeric vaccine of Vakharia et al. reads on a NNV vaccine.

Claims 6, 7, 15 and 16 are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Laurie Scheiner/LAS
May 3, 2005

LAURIE SCHEINER
PRIMARY EXAMINER